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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,413	04/19/2001	Marco Falciani	203970US6PCT	5932

7590

04/22/2003

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EXAMINER

BASICHAS, ALFRED

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 04/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,413

Applicant(s)

FALCIANI ET AL.

Examiner

Alfred Basichas

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater (5385564), Scharf (5484431), or Beigler (4282863), which disclose substantially all of the claimed limitations. Slater, Scharf, and Beigler disclose a hermetically sealed polyolefin bag for preserving and transporting a soluble sterile product in powder form and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product. Slater, Scharf, and Beigler do not specifically state that the water should only be added to a volume less than the capacity of the bag. Adding less than the full capacity of the bag in order to allow for room to shake is well within the knowledge and ability of one of ordinary skill in the art; it is a simple matter of common sense. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided for only filling the bag with less than the capacity of the bag or 1.5 to 2 times the volume of the ready to use solution into the inventions of Slater, Scharf, and Beigler in order to provide room to shake the contents of the bag.

5. Claims 6, 9, 12, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shumann (3726276) in view of Slater (5385564), Scharf (5484431), or Beigler (4282863). Shumann discloses a sealed plastic bag 13 for preserving and

transporting a soluble product 51 in powder form (col. 3, lines 24-26) and for reconstituting in the bag a ready to use solution with a predetermined concentration of the sterile product (col. 3, line 59 – col. 4, line 8). While Shumann does not specifically recite that the product is sterile, it is inherent considering the intended use of the product (col. 4, lines 11-16). In addition, Shumann does not specifically recite that the bag is hermetically sealed or made from polyolefin. Slater, Scharf, and Beigler teach bags for carrying sterile product that are hermetically sealed and made of polyolefin, so as to keep the product from spoiling or being contaminated. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided hermetic sealing and polyolefin material as taught by Slater, Scharf, and Beigler into the invention disclosed by Shumann, so as to keep the product from spoiling or being contaminated.

6. Claims 7, 8, 10, 11, 13, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shumann (3726276) in view of Slater (5385564), Scharf (5484431), or Beigler (4282863), which combination discloses the claimed invention except for the claimed range or requiring multiple doses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the claimed range and multiple doses into the invention disclosed by the above mentioned

combination, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

7. Applicant's arguments with respect to claims 6-17 have been considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alfred Basichas whose telephone number is 703 306 3476. The examiner can normally be reached on Flexible.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703 308 0101. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9302 for regular communications and 703 872 9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0861.

April 17, 2003


Alfred Basichas
703 306 3476